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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,118

03/24/2005

Frank Cuttitta

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/529,118

Applicant(s)

CUTTITTA ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5/29/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 10-19 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10-19 and 21-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 5/29/07 wherein claims 1, 5, 14, 22, 24, and 25 are amended and claims 6-9 and 20 are canceled.

**Note:** Claims 1-5, 10-19, and 21-27 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments and/or amendment filed 5/29/07 to the rejection of the claims made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

### **112 Second Paragraph Rejections**

The rejection of claims 5, 10-21, and 24-27 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention are MAINTAINED-IN-PART for the reasons set forth below.

I. The rejection of claims 1-4 as having essential steps missing is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

II. The rejection of claims 20 and 24 as being ambiguous because of the term 'small' is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

III. The rejection of claim 22 as having essential steps missing is WITHDRAWN because Applicant has amended the claim to overcome the rejection.

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IV. The rejection of claim 14 as having essential steps missing is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

V. The rejection of claims 1-5, 10-19, and 21-27 are MAINTAINED for reasons of record in the office action mailed 2/27/07 and those reasons set forth below.

Applicant asserts that the claims have been amended to overcome the rejection by incorporating 'SEQ ID NO 4' into the claims.

Applicant's arguments are non-persuasive because there are still some inconsistencies in the claims. In particular, in some portions of the claims, the term 'AM' is disclosed, in others 'AM (11-22)', in some others 'AM (11-22) SEQ ID NO 4', and still in others 'peptide AM (11-22) SEQ ID NO 4'. Thus, the claims are ambiguous because it is unclear if all the sequences are the same or if Applicant is claim variations of the sequences.

### **103 Rejections**

The rejection of claims 1, 2, 5, 10, 13-18, 21-25, and 27 under 35 USC 103(a) as being unpatentable over Kitamura et al (Peptides, 2001, Vol. 22, pages 1713-1718 (document listed on IDS) in view of Fritzberg et al (US Patent No. 5,175,343) is MAINTAINED for reasons of record in the office action mailed 2/27/07 and those set forth below.

Applicant asserts that the cited prior art does not disclose AM (11-22), but rather discloses a vasoactive peptide AM (11-26) that is 33% longer than AM (11-22) and differs at position 19. In addition, Applicant asserts that the peptide of the instant invention is unexpectedly superior to that of the cited prior art. Furthermore, Applicant

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asserts that prolonged kinetics of the activity of the AM (11-22) could not have been predicted from the peptide of the prior art.

Applicant's arguments have been considered, but are not deemed persuasive for reasons of record and those set forth below. In particular, Applicant's claims read '...effective amount of peptide AM (11-22)...'. The interpretation of the claim is that it is not limited to the specific sequence of AM (11-22). For example, if one has the two sentences below:

**(Sentence 1)** A composition comprising peptide AM (11-22).

**(Sentence 2)** A composition comprising the peptide AM (11-22).

The two sentences result in claims of very different scope. The first sentence encompasses peptides that comprise the full length or any portion of peptide AM (11-22). The second sentence claims only peptide sequences that comprise the full length of peptide AM (11-22) with or without additional sequences at either or both ends.

If the claim language is changed to closed (replacing 'comprising' with 'consisting of'), the interpretation of the claim changes.

**(Sentence 3)** A composition consisting of peptide AM (11-22).

**(Sentence 4)** A composition consisting of the peptide AM (11-22).

Sentence 3 would encompass any peptide sequence wherein peptide AM (11-22) is present. Sentence 4 would be limited to the peptide sequence as specified by peptide AM (11-22) and nothing more or less. Hence, the rejection is deemed proper.

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If Applicant intends the claims to read only on peptide AM (11-22) only it is respectfully suggested that the phrase 'consisting of the peptide AM (11-22)' be used in all the appropriate claims.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

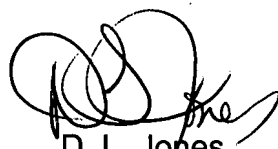
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'D. L. Jones', is positioned above the printed name.

D. L. Jones  
Primary Examiner  
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July 29, 2007